ABSTRACT

This invention provides a process of sterilizing a medical device, and preferably the contents of a sealed container which comprises said medical device, comprising the step of exposing said medical device to ultraviolet radiation whereby the D_{value} of Bacillus stearothermophilus (ATCC 7953) is at least 3.9 mJ/cm^2 ultraviolet radiation in the range of 240-280 nm to the spore. Further, this invention provides a process of sterilizing a medical device comprising the step of subjecting said medical device to ultraviolet radiation wherein the minimum total energy density of said ultraviolet radiation in the range of 240-280 nm which reaches the microorganisms present on said medical device is at least 18 mJ/cm^2.

This invention further provides an apparatus for delivering UV radiation to a medical device for sterilization comprising a radiation source and a reflector for said radiation source wherein said reflector directs radiation from said radiation source such that at least 3 J/cm^2 broad spectrum radiation of which at least 50 mJ/cm^2 of said radiation is UV radiation in the range of 240-280 nm to a treatment area for said medical device, said treatment area is at the focal plane of said reflector. This invention provides a process and apparatus in which sterilization can be achieved in less than 20 seconds, preferably less than 15 seconds, more preferably in less than 5 seconds. The process and apparatus are efficient and continuous.